

## FLEXIBLE CONTAINMENT CHARGING DEVICE

Background of the Invention

The present invention relates to a film based material transfer device, with an integrated restraint system that protects the process operator and environment from the potent or otherwise harmful, and/or toxic substances contained within it, as well as a method for producing the film based material transfer device.

Description of the Related Art

Material transfer devices for potent compounds used in the pharmaceutical industry are typically constructed of rigid polymer bottles that can be integrated directly to a passive half of a split butterfly valve. These devices allow filling and/or discharging of potent substances in a contained manner when mated to the active half of a split butterfly valve. The rigid polymer bottles are strong enough to withstand limited pressurization during operation of the valve, during both filling and discharge.

However, such systems present problems with respect to product flow when certain powder substances are used, for example, fine chemicals, toxic and/or hazardous waste, pharmaceutical dry powder compositions, pharmaceutical intermediate processing compounds, laboratory and pilot plant pharmaceutical compounds, as well as pharmaceutical wet-cake material. Additionally, conventional containment charge devices prohibit visual verification that the system has been completely emptied of, or completely filled with, the potent product.

Other conventional transfer devices utilize a film enclosure that integrates to a sanitary fitting. This fitting can also be connected to a passive half of a split butterfly valve and used as above. While the film may be transparent to allow visual verification that the potent substance has been discharged, and the flexibility may allow for manual manipulation of the system to enhance product flow out of the device, such systems may only be used on a small product volume basis due to requirements such as material strength. Additionally, use of the conventional film enclosures is generally limited to non-pressurized environments to avoid the potential rupture of the film, breach of the containment device and the potential for release of the harmful, often toxic, material into the environment.

Despite the advantages of the conventional containment discharging devices, such systems provide no means of grounding to eliminate any static electric charge that can build-up while filling or discharging the substance, thus presenting a hazardous situation in solvent vapor environments.

Therefore, there exists a need in the art for a containment device which is integrated with a sanitary valve, that can withstand pressurizations during filling and/or discharge, as well as being flexible enough to permit manual manipulation to assist the filling and/or discharge, while simultaneously permitting visual inspection of the contents disposed therein.

### Summary of the Invention

A process for integrating a flexible film based liner into a woven fabric restraint has been developed to transfer potent or toxic substances in a contained manner. The integration of the fabric restraint allows the system to withstand limited pressurization. The restraint not only adds strength to the system while maintaining flexibility but also protects the liner from breach of containment due to puncture. The film liner maybe welded to a polymer sanitary fitting that can be integrated to a passive half of a split butterfly valve. The flexible nature of the device allows the operator to manually massage the potent powder substance to enhance flow characteristics when emptying the device. The restraint can be fabricated of conductive or non-conductive material. If constructed from conductive material this will allow grounding of the device to eliminate static charge build-up while filling or discharging.

### Brief Description of the Drawings

Fig. 1 is a representation of the flexible film liner assembly that forms the inner, containment layer of the charging device.

Fig. 1a is a top view of the structure of Fig. 1.

Fig. 2 is a representation of the woven fabric restraint assembled with the film liner. This provides both a pressure retaining capability of the system and protection from damage.

Fig. 2a is a top view of the structure of Fig. 2.

Fig. 3 is a section detail along lines A-A of Fig. 2 illustrating the stitched integration of the film liner to the restraint along with the lifting loop.

#### Detailed Description of the Preferred Embodiments

The flexible charging device 1 of the invention utilizes an inner liner 10 of Fig. 1. Typically, inner liner 10 is fabricated from a thin impermeable film of polymer material. The shape of inner liner 10 may be constructed from patterns that are thermally welded or sewn to form a sealed structure together at joints 11 or provided as a single unit, having no welded joints. Inner liner 10 is also, preferably, thermally welded to a sanitary fitting 12. For example, inner liner 10 may contain one or more sewn seams as described in U.S. Application No. 09/666,845, herein incorporated by reference in its entirety. However, inner liner 10 may be joined to sanitary fitting 12 by any known, or later developed, method, including sewing or joining with an adhesive. This assures a totally sealed fabrication that eliminates crevices where toxic substance can get trapped. Although Fig. 1 depicts inner liner 10 as having a specific shape, it is understood that, preferably, inner liner 10 is a flexible material, conforming generally to the shape of its contents and/or the container.

Sanitary fitting 12 may be any structure capable for forming a substantially sealed joint with a filling device (not shown) such as an active or passive half split of a butterfly valve, and is preferably formed from a thermoplastic, such as a polyolefin. In one embodiment, sanitary fitting 12 is provided with sealing means, such as O-rings or locking members, to form an airtight seal with the filling device. Optionally, sanitary fitting 12 includes means for sealing to prevent the escape of any material contained in flexible charging device 1, i.e., the load.

Although a wide variety of materials are suitable for inner liner 10, typically, inner liner 10 is constructed of a thermoplastic film, such as a polyolefin. In addition, inner liner 10 may also include one or more barrier layers. Such barrier layers can prevent chemical fluid or vapor introduction/escape, light inhibition, or other barrier layers to prevent contact of the contents of the liner with the environment.

In one embodiment, inner liner 10 may be any thin flexible material, e.g., a woven or non-woven fabric, coated with at least one polymer layer, and optionally, a chemical barrier layer. When inner liner 10 is such a structure, the thin flexible material need not be

impervious to the material disposed within flexible charging device 1, as the polymer layer should perform such a function. If the thin flexible material, coated with a polymer, provides the structure necessary to maintain the integrity of inner liner 10, the thickness of the polyolefin layer may be reduced. Typically, the polymer layer of inner liner 10 is a thermoplastic material, such as a polyolefin, for example, polyethylene, polypropylene or polybutylene.

As shown in Figs. 2 and 3, inner liner 10 is integrated to an outer fabric restraint 13. In one embodiment, fabric restraint 13 is provided with window 18, integrated into the side. A user may use window 18 to verify that all the contained substance has been emptied from the device during discharge. Window 18 is typically sewn over an opening in fabric restraint 13, using a thread, or may simply be thermally sealed to fabric restraint 13. Although inner liner 10 is a flexible material, which, in most situations will conform to the shape provided by the contents thereof, window 18 may include a second element providing observation through inner liner 10 as well. Accordingly, window 18 may include a seam, joining an aperture through both fabric restraint 13 and inner liner 10.

Similar to inner liner 10, fabric restraint 13 is preferably a polymeric material, such as a homopolymer or copolymer or blends of plastic material, such as a thermoplastic material, typically a polyolefin. The polyolefin may be an optionally substituted linear or branched material, for example, polyethylene, polypropylene or polybutylene. Although fabric restraint 13 may be formed from the same material as inner liner 10, typically, fabric restraint 13 is a woven polypropylene fabric.

In one embodiment, fabric restraint 13 is conductive. This may be accomplished by incorporating a small amount of metallic or conductive material, such as a powder, flakes or fibers, into the structure of fabric restraint 13, or optionally, by providing fabric restraint 13 with a plurality of conductive elements, such as wires, spokes or threads. Additionally, it is considered within the scope of the invention to incorporate other conductive material, other than metal, in the structure of fabric material 13, for example, carbon black or graphite particles. In order to form a path to ground, flexible charging device 1 may be provided, for example, with a grounding loop 19, sewn into fabric restraint 13. By forming fabric restraint 13 from a conductive material, any charge developed inside fabric restraint 13 may easily be discharged. If the fabric restraint 19 is not provided with conductive material, material

disposed inside flexible charging device 1 may ignite or cause other dangerous situations, such as explosions.

Fig. 3 shows a cross-section of the top of flexible charging device 1 (when in a discharge position) along the line indicated at A-A in Fig. 2. Inner liner 10 is placed inside fabric restraint 13 and mechanically attached by a stitching 15 through both a hem 14 on fabric restraint 13 and, for example, a welded seam 16 at the top of inner liner 10. Integration of inner liner 10 to fabric restraint 13 will assure that the liner remains in place and prevent the liner from collapsing and hampering product discharge. In order to reduce any risk of breaching containment, it is preferable to provide stitching 15 only where necessary, i.e., at weld seam 16 and/or window 18.

A lifting loop 17 is also optionally provided. Lifting loop 17 may be captured in stitching 15 at the top of the device, or attached in any other manner to flexible charging device 1. For example, lifting loop may be welded to the side of fabric restraint 13 or joined to sanitary fitting 12. This gives the user a means of suspending the device during unloading.

It is additionally considered within the scope of the invention to integrate grounding loop 19 with lifting loop 17, or to provide lifting loop 17 with a hinge, such that it may also be used to maintain flexible charging device 1 to permit suspension during filling and discharging. Alternatively, flexible charging device 1 may be provided with a second lifting loop 17 for such a purpose.

As described herein, flexible charging device 1 may be used to contain any variety of materials, such as powders, flakes, emulsions and liquids, and need not be limited to containing harmful or toxic materials. However, flexible charging device is particularly designed to contain and/or transport materials such as fine chemicals, toxic and/or hazardous waste, pharmaceutical compositions in dry or powder form, intermediate materials for pharmaceutical processing, and laboratory and pilot plant compounds, as well as pharmaceutical wet-cake material.

Although we have described the invention in connection with exemplary embodiments, the invention is not so limited and modifications thereof may be made by those skilled in the art without departing from the scope of the invention.